REMARKS

The Office Action has been carefully studied. Claims 5-8 and 12 are allowed. Claims 5-12, 15-17 and 19 presently appear in this application and define patentable subject matter warranting their allowance.

The interview among the undersigned, representing applicants, and Examiners Zeman and Wortman on January 10, 2001, is hereby gratefully acknowledged. The undersigned wishes to thank the examiners for the courtesies extended during this interview. Although no agreement was reached on the ultimate question of patentability, it is the impression of the undersigned that amendment of claims 9, 11, 15, and 19 to insert the recitation of "by passive immunotherapy" in the preamble would be acceptable and is believed to overcome the outstanding §112, first paragraph rejection. The arguments presented at the interview are also incorporated herein.

Claim 10 was indicated as being objected to as depending from a rejected claim. However, claim 10 is dependent from claim 5, an allowed claim. Therefore, claim 10 is believed to also be allowed.

Claims 9, 11, 15-16 and 19 have been rejected under 35 U.S.C. §112, first paragraph, because the examiner indicates that the specification, while being enabling for the treatment of HBV infection, does not reasonably provide

enablement for reducing the occurrence of HBV infections in a population of individuals, which recitation is interpreted by the examiners to be a definition of "prevention". The examiner takes the position that the rejected claims are directed to a prophylactic antibody vaccine composition. This rejection is respectfully traversed.

Applicants' clarify that the rejected antibody compositions are not vaccine compositions. The pharmaceutical compositions according to claims 9 and 15 are meant to be used in passive immunotherapy, which is not supposed to elicit a long term immune response. Applicants' further clarify that there is a conceptual difference between administering a vaccine (active immunotherapy/immunization) and administering antibodies (passive immunotherapy/immunization). A vaccine contains an antigen that is administered to the individual to generate an antibody response in the host. Such a response takes time to generate but then lasts for a long time. On the other hand, passive immunotherapy, which includes giving antibodies, has an immediate effect but the antibodies must be given continuously in order to keep their effect since antibodies are degraded with time in the patient's sera.

Passive immunotherapy is of course well known in the art and is frequently practiced in medicine. It is actually the recommended therapy for patients undergoing liver

transplantation, and reference is made in the specification, bottom of page 1, to the use of HBV antisera in delaying and reducing recurrent HBV infection by passive immunization (immunotherapy). Such patients undergoing liver transplantation receive a polyclonal preparation of human anti-HBV antibodies immediately after transplantation and this treatment is maintained once every several weeks for life in order to prevent re-infection of the transplanted liver with hepatitis B virus.

Rejected claims 9, 11, 15, and 19 are now amended to recite in the preamble "for reducing the occurrence of HBV infections in a population of individuals by passive immunotherapy". It is submitted that passive immunotherapy with antibodies is a well-known and well-practiced procedure, particularly for protecting against re-occurrence of Hepatitis B infection after liver transplantation. Accordingly, the presently claimed pharmaceutical compositions containing anti-HBV antibodies and method of reducing the occurrence of HBV infections in a population of individuals by passive immunotherapy with specific anti-HBV antibodies are well-enabled to those of skill in the art.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

In view of the above, the present claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By _____
Allen C. Yun
Registration No. 37,971

ACY:pr

624 Ninth Street, N.W.
Suite 300
Washington, D.C. 20001
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
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